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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	6

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,812	Applicant(s) GREFF, RICHARD J.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 08/28/2002.

Claims 1-16 are included in the prosecution.

Specification

1. The use of the trademark "Actifoam™" and "Gelfoam" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Minor Informalities

3. Claim 9 recites "the composition is bioadsorbable" instead of "bioabsorbable". With careful review of the entire specification, for example first paragraph of page 7, bioabsorbable composition has been discloses, thus, it seems to be a typographical error. For examination purposes, the claim is treated as "the composition is bioabsorbable".

4. In claim 12, second line, the preposition "by" between the terms "gelatin" and "a solution" appears to be mistakenly inserted.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 3, 6, 7, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite the limitation "foaming" in claim 1. There is insufficient antecedent basis for this limitation in claim 1.

Claims 6 and 7 recite the limitation "foaming" in claim 5. There is insufficient antecedent basis for this limitation in claim 5.

Claim 15 recites the limitation "the sponge" in claim 1. There is insufficient antecedent basis for this limitation in claim 1.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-6, 8-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2002/0042378 ('378) with the effective filing date of June 10, 1999.

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of the wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. The wetting agent is impregnated with (claim 2) or mixed with (claim 3) or coated on (claim 4) the gelatin. Claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration, i.e. prior to use, by mixing (claim 6), or coating the wetting agent into the gelatin (claim 8). The composition is bioabsorbable (claim 9). The composition further comprises : growth factor, thrombus enhancing agents or antimicrobial agents (claim 10). The

wetting agent forms 0.1 to 10% of the gelatin (claim 11). Claim 12 recites the coating achieved by applying to the surface of the gelatin a solution consisting of the wetting agent and solvent in a concentration of 1-20%, then the solvent removed by evaporation of the solvent (claim 13). The composition is in form of sterilized and packaged sponge (claim 15).

PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5: 0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2: 0016). The most preferred cross-linked polymer is gelatin (page 3: 0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. The non cross-linked polymer solublizes when exposed to blood and releases the cross-linked polymer so that it can hydrate as it absorbs water from the blood, that reads on the intended function of the wetting agent (page 1: 0012). Decreasing the hydration time of the cross-linked gelatin that claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration. The cross-linked gelatin particles are dispersed in a solution comprising non cross-linked polymer and the polyethylene glycol and well mixed before drying as recited in claims 3

and 6; that also reads on impregnating the wetting agent with gelatin because the gelatin particles are suspended in the wetting agent as in claim 2; and reads on coating the wetting agent on the surface of gelatin because the particles of gelatin are surrounded by the suspension of the wetting agents as claimed in claims 4 and 8; and example 2 shows that the dispersion of the cross-linked and non cross-linked polymers and plasticizer is performed prior to the formation of the sponge, i.e. prior to foaming (page 1:0012; page 2: 0018; page 4: 0035; page 6: 0045). The cross-linked polymers are degradable, i.e. bioabsorbable as claimed in claim 9 (page2: 0013). The composition further comprising bioactive agents including blood clotting agents such as thrombin, antibiotics, bacteriostatic and bacteriocidal agents, and antiviral, that reads on claim 10 (page 2: 0012; page 4: 0036). Example 2 of the reference shows that the amount of cross-linked gelatin in the composition is 1-4 grams, and the amount of polyethylene glycol is 0.1-2%, therefor, if the dispersion comprises 2 gm of gelatin that is to be 2000 mg in 100 ml and 1% of polyethylene glycol that is 100 mg per 100 ml, then the amount of polyethylene glycol is calculated to form 5 wt.% of the cross-linked gelatin, reads on the amount claimed in claim 11 (example 2: pages 5-6). The method of making the material of the reference includes dispersing the cross-linked gelatin particles in a solution comprising polyethylene glycol (wetting agents) in a concentration of 0.1-2% and well mixing the suspension before drying, i.e. before evaporating the solvent as in claims 12 and 13 (page 3: 0021; page 4: 0035; page 6: 0045).). The composition of the reference can be in the form of sponge (page 4: 0035) that is provided in sterile packs, as claimed in claim 15 (page 3: 0020).

The limitation of claims 1-6, 8-13 and 15 are met by PGPB '378.

9. Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2003/0088271 ('271).

PGPB '271 disclosed a kit form for delivery of absorbable sponge material to the puncture site to achieve hemostasis (page 2 and 3: 0058). The kit comprises absorbable sponge material in the form of pledget that is illustrated by number 40 in the drawings, and a syringe that is illustrated by number 50 of the drawings (see figures 3-5 in particular). The pledget gets hydrated in chamber 34, that means that the pledget is present in the kit as non-hydrated, (page 3: 0068, 0069; figures 3-5;). Thus, the kit comprises a syringe and non-hydrated pledget. The pledget consisting of cross-linked gelatin and can be pre-soaked with a beneficial agent, reads on wetting agent (page 5: 0083; page 10: 0137). The reference further disclosed the pledget provided with rapidly dissolved tip made of biocompatible, non-toxic, and non-immunogenic polymers such as polyvinyl pyrrolidone, polyethylene oxide, and carbowax, and this also reads on pledget consisting of cross-linked gelatin and wetting agent as claimed in claim 16 (page 10: 0141).

The limitation of claim 16 is met by PGPB '271.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '378.

The teaching of the PGPB '378 is discussed under 102 rejection above.

However, the reference does not teach impregnating the gelatin with the wetting agent as in claim 7, or the amount of the wetting agent in the gelatin composition after evaporation of the solvent.

It is expected that if the cross-linked gelatin is in the porous form, then the wetting agent is added to the porous material and mixed, the porous material will be impregnated with the wetting agent. Since applicant not claiming any particular form of the cross-linked gelatin, thus, mixing would read on impregnated depending on the form of the gelatin used in the instant invention.

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to obtain a composition comprising cross-linked gelatin and wetting agent as disclosed by PGPB '378 and select the method of incorporating the wetting agent into the gelatin such as mixing, impregnating or coating depending on the form of the cross-linked gelatin, and adjust the degree of drying of the final product to

achieve a desired concentration of the wetting agent in the composition, with reasonable expectation of success having a hemostatic composition that stop bleeding at the site of application within a reasonable time.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali